

Remarks/Arguments

The prior office action indicated the status of the claims is as follows: claims 1-8 and 18-19 are under examination; and claims 9-17 are withdrawn from examination. Claims 1-8 stand rejected as allegedly not enabled. A specific rejection was not provided for claims 18 and 19. However, the office action indicated that no claim is allowed.

The present amendment cancels claims 9-17 without prejudice to future prosecution. Claims 9-17 are directed to non-elected subject matter.

Interview Summary

A telephonic interview was conducted between the examiner and applicant's representative (Sheldon Heber) on April 19, 2004. As described in the examiner's Interview Summary, the interview was initiated by the examiner and concerned applicant's response to a sequence listing requirement contained within an office action. The interview did not involve any claims or a discussion of the prior art.

The sequence listing requirement was given an one month date, whereas the time for responding to the office action was three months. Applicant complied with the sequence listing requirement within the one month time frame and was planning to subsequently follow up with a response to the other issues raised in the office action.

The filing of the sequence listing response started the time frame for the examiner's response. The examiner requested the applicant provide a complete response to the office action by May 17, 2004. A complete response was subsequently filed May 6, 2004.

35 USC § 112, First Paragraph (Enablement)

Claims 1-8 stand rejected as allegedly not enabled. The examiner argues: (a) the application does not teach a nexus between the level of caspase 3 activity measured and viral activity; (b) the applicant has not provided any evidence of a correlation between viral activity and caspase 3 activity; and (c) the application has not taught how to account for apoptosis that occurs as a result of environmental conditions. This rejection is respectfully traversed.

The application provides sufficient guidance allowing the skilled artisan to practice the invention without undue experimentation. The provided guidance include examples showing a

correlation between viral activity and caspase 3 activity, the reproducibility of the caspase 3 assay, and the linearity of the caspase 3 assay.

A correlation between viral activity and caspase 3 signal is illustrated in the application using different viral dilutions and by comparing results obtained with the caspase 3 assay to results obtain with a plaque forming unit (PFU) assay. The effect of different viral dilutions is summarized in Tables 5 and 6. (The application on pages 11, line 5 to page 12, line 2.) As the multiplicity of infection was decreased through viral dilution, caspase 3 signal correspondingly decreased. Figures 4-6 provide results comparing the caspase 3 assay to a PFU assay.

The reproducibility of the assay is illustrated in the application by repeating the assay using three vials of the same sample. (The application at pages 10, line 19 to page 11, line 4, including Table 4). Table 4 illustrates that, overall, the assay is reproducible.

The linearity of the caspase 3 assay is illustrated by measuring caspase 3 activity following viral induction. (The application at page 9, lines 1-11 and Figures 2a and 2b.) Figure 2a illustrates that the assay is linear for at least one hour using measles virus. Figure 2b illustrates that the assay is linear for at least 75 minutes using mumps virus.

With respect to the effect of apoptosis, the skilled artisan selects the conditions under which the assay is performed. The virus itself can be taken from different environments and assayed under suitable conditions. The examples provided in the application illustrate conditions where apoptosis does not prevent the assay from being used.

Please charge deposit account 13-2755 for fees due in connection with this amendment. If any time extensions are needed for the timely filing of the present amendment, applicant petition for such extensions and authorize the charging of deposit account 13-2755 for the appropriate fees.

Respectfully submitted,

By *Sheldon O. Heber*
Sheldon O. Heber
Reg. No. 38,179
Attorney for Applicant(s)

Merck & Co., Inc.
P.O. Box 2000
Rahway, New Jersey 07065-0907
(732) 594-1958